

Gerald Krovatin
KROVATIN KLINGEMAN LLC
744 Broad Street, Suite 1903
Newark, NJ 07102
Tel: (973) 424-9777
Fax: (973) 424-9779
Attorneys for Plaintiff Fournier
Laboratories Ireland Ltd.

William J. Heller
Jonathan M.H. Short
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Tel: (973) 622-4444
Fax: (973) 624-7070
Attorneys for Plaintiff Elan Pharma
International Ltd.

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ELAN PHARMA)
INTERNATIONAL LTD. and)
FOURNIER LABORATORIES)
IRELAND LTD.,)
)
Plaintiffs,)
)
v.)
)
LUPIN LIMITED and)
LUPIN PHARMACEUTICALS,)
INC.,)
)
Defendants.)
_____)

C.A. No. 2:09-cv-01008-GEB-MCA

**PLAINTIFFS' REPLY TO LUPIN LIMITED AND LUPIN
PHARMACEUTICALS, INC.'S COUNTERCLAIMS**

Elan Pharma International Ltd. (“Elan”) and Fournier Laboratories Ireland Ltd. (“Fournier”), by their attorneys, reply to the Counterclaims of Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, “Lupin”) as follows:

COUNTERCLAIMS

The Parties

1. Lupin Ltd. is a corporation organized and existing under the laws of India, having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (W), Mumbai 400 051, India.

ANSWER: Admitted.

2. LPI is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland, 21202.

ANSWER: Admitted.

3. Elan Pharma International Ltd. purports to be an Irish corporation having a principal place of business at Monksland, Athlone, Co. Westmeath, Ireland.

ANSWER: Admitted.

4. Fournier Laboratories Ireland Ltd. purports to be an Irish corporation having its principal place of business at Ann Grove, Carrigtwohill, Co. Cork, Ireland.

ANSWER: Admitted.

Jurisdiction and Venue

5. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (“MMA”) (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

ANSWER: Paragraph 5 contains legal conclusions that require no answer. To the extent that a response is required, Elan and Fournier admit that they have charged Lupin with infringing claims of U.S. Patent Nos. 7,276,249 and 7,320,802, and that Lupin has raised affirmative defenses and declaratory judgment counterclaims of non-infringement and invalidity. Elan and Fournier otherwise deny the remaining allegations set forth in paragraph 5.

6. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory

Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

ANSWER: Paragraph 6 contains legal conclusions that require no answer. To the extent that a response is required, Elan and Fournier admit that they have charged Lupin with infringing claims of U.S. Patent Nos. 7,276,249 and 7,320,802, and that Lupin has raised affirmative defenses and declaratory judgment counterclaims of non-infringement and invalidity. Elan and Fournier otherwise deny the remaining allegations set forth in paragraph 6.

7. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because Plaintiffs/Counterclaim-Defendants have purposefully availed themselves of the rights and privileges of this forum by suing Lupin in this District, and because Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular and systematic contacts with, this District.

ANSWER: Elan and Fournier admit that this Court has personal jurisdiction over them for purposes of these counterclaims, and that they have sued Lupin in this judicial district. Elan and Fournier deny the remaining allegations set forth in paragraph 7.

8. Venue for these Counterclaims is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

ANSWER: Elan and Fournier admit that venue for purposes of these counterclaims is proper in this Court. Elan and Fournier deny the remaining allegations set forth in paragraph 8.

Patents-In-Suit

9. On or about April 23, 2002, the United States Patent and Trademark Office (“PTO”) issued U.S. Patent No. 6,375,986 B1 (“the ’986 patent”), entitled “Solid Dose Nanoparticulate Compositions Comprising A Synergistic Combination Of A Polymeric Surface Stabilizer And Dioctyl Sodium Sulfosuccinate,” to Niels P. Ryde and Stephen B. Ruddy. A true and correct copy of the ’986 patent is attached hereto as Exhibit A.

ANSWER: Elan and Fournier admit that on or about April 23, 2002, the United States Patent and Trademark Office issued United States Patent No. 6,375,986 (“the ’986 patent”), entitled “Solid Dose Nanoparticulate Compositions Comprising a Synergistic Combination of a Polymeric Surface Stabilizer and Dioctyl Sodium Sulfosuccinate.” Elan and Fournier further admit that what purports to be a copy of the ’986 patent is attached to Lupin’s counterclaims as “Exhibit A.”

10. On or about October 2, 2007, the PTO issued U.S. Patent No. 7,276,249 B2 (“the ’249 patent”), entitled “Nanoparticulate Fibrate Formulations,” to Tuula Ryde, Evan E. Gustow, Stephen B. Ruddy, Rajeev Jain, Rakesh Patel and

Michael John Wilkins. A true and correct copy of the '249 patent is attached hereto as Exhibit B.

ANSWER: Elan and Fournier admit that on or about October 2, 2007, the United States Patent and Trademark Office issued United States Patent No. 7,276,249 (“the '249 patent”), entitled “Nanoparticulate Fibrate Formulations.” Elan and Fournier further admit that what purports to be a copy of the '249 patent is attached to Lupin’s counterclaims as “Exhibit B.”

11. On or about January 22, 2008, the PTO issued U.S. Patent No. 7,320,802 B2 (“the '802 patent”), entitled “Methods of Treatment Using Nanoparticulate Fenofibrate Compositions,” to Tuula Ryde, Evan E. Gustow, Stephen B. Ruddy, Rajeev Jain, Rakesh Patel and Michael John Wilkins. A true and correct copy of the '802 patent is attached hereto as Exhibit C.

ANSWER: Elan and Fournier admit that on or about January 22, 2008, the United States Patent and Trademark Office issued United States Patent No. 7,320,802 (“the '802 patent”), entitled “Methods of Treatment Using Nanoparticulate Fenofibrate Compositions.” Elan and Fournier further admit that what purports to be a copy of the '802 patent is attached to Lupin’s counterclaims as “Exhibit C.”

12. The '986 patent, the '249 patent and the '802 patent are listed in FDA’s Orange Book in connection with TRICOR®, as patents that allegedly

“claim[] the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.”

ANSWER: Elan and Fournier admit that the '986, '249, and '802 patents, in addition to other patents, are listed in the Orange Book in association with TRICOR[®] 145 mg and 48 mg. Elan and Fournier otherwise deny the allegations in paragraph 12.

13. On information and belief, Plaintiffs/Counterclaim-Defendants purport and/or claim to own and/or license, and/or to have the right to enforce, the '986 patent, the '249 patent and the '802 patent.

ANSWER: Elan and Fournier admit that Elan is the owner by assignment of the '986 patent. Elan and Fournier further admit that Elan and Fournier are the owners by assignment of the '249 and '802 patents. Elan and Fournier otherwise deny the allegations in paragraph 13.

14. On or about March 6, 2009, Plaintiffs/Counterclaim-Defendants filed suit against Lupin in this District alleging infringement of the '249 patent and the '802 patent.

ANSWER: Admitted.

COUNT I
(Declaration of Non-Infringement of the '986 Patent)

15. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-14.

ANSWER: Lupin's incorporation by reference of "Paragraphs 1-14" requires no response. To the extent a response is required, Elan and Fournier hereby incorporate their responses to the allegations in paragraphs 1-14 above.

16. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the noninfringement of the '986 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

ANSWER: Elan and Fournier are without sufficient knowledge to admit or deny the averments contained in paragraph 16.

17. The manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '986 patent.

ANSWER: Elan and Fournier are without sufficient knowledge to admit or deny the averments contained in paragraph 17.

18. Lupin is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '986 patent.

ANSWER: Elan and Fournier are without sufficient knowledge to admit or deny the averments contained in paragraph 18.

COUNT II
(Declaration of Invalidity of the '986 Patent)

19. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-18.

ANSWER: Lupin's incorporation by reference of "Paragraphs 1-18" requires no response. To the extent a response is required, Elan and Fournier hereby incorporate their responses to the allegations in paragraphs 1-18 above.

20. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the invalidity of the claims of the '986 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

ANSWER: Paragraph 20 states a legal conclusion for which no response is required. To the extent that a response is required, Elan and Fournier admit that an actual controversy exists regarding the validity of the

'986 patent. Elan and Fournier otherwise deny the allegations in paragraph 20.

21. The claims of the '986 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq.*

ANSWER: Denied.

22. Lupin is entitled to a declaration that the claims of the '986 patent are invalid.

ANSWER: Denied.

COUNT III
(Declaration of Non-Infringement of the '249 Patent)

23. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-22.

ANSWER: Lupin's incorporation by reference of "Paragraphs 1-22" requires no response. To the extent a response is required, Elan and Fournier hereby incorporate their responses to the allegations in paragraphs 1-22 above.

24. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the noninfringement of the '249 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

ANSWER: Paragraph 24 states a legal conclusion for which no response is required. To the extent that a response is required, Elan and Fournier admit that an actual controversy exists regarding Lupin's infringement of the '249 patent. Elan and Fournier otherwise deny the allegations in paragraph 24.

25. The manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '249 patent.

ANSWER: Denied.

26. Lupin is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '249 patent.

ANSWER: Denied.

COUNT IV
(Declaration of Invalidity of the '249 Patent)

27. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-26.

ANSWER: Lupin's incorporation by reference of "Paragraphs 1-26" requires no response. To the extent a response is required, Elan and

Fournier hereby incorporate their responses to the allegations in paragraphs 1-26 above.

28. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the invalidity of the claims of the '249 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

ANSWER: Paragraph 28 states a legal conclusion for which no response is required. To the extent that a response is required, Elan and Fournier admit that an actual controversy exists regarding the validity of the '249 patent. Elan and Fournier otherwise deny the allegations in paragraph 28.

29. The claims of the '249 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq.*

ANSWER: Denied.

30. Lupin is entitled to a declaration that the claims of the '249 patent are invalid.

ANSWER: Denied.

COUNT V
(Declaration of Non-Infringement of the '802 Patent)

31. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-30.

ANSWER: Lupin's incorporation by reference of "Paragraphs 1-30" requires no response. To the extent a response is required, Elan and Fournier hereby incorporate their responses to the allegations in paragraphs 1-30 above.

32. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the noninfringement of the '802 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

ANSWER: Paragraph 32 states a legal conclusion for which no response is required. To the extent that a response is required, Elan and Fournier admit that an actual controversy exists regarding Lupin's infringement of the '802 patent. Elan and Fournier otherwise deny the allegations in paragraph 32.

33. The manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '802 patent.

ANSWER: Denied.

34. Lupin is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s

ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '802 patent.

ANSWER: Denied.

COUNT VI
(Declaration of Invalidity of the '802 Patent)

35. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-34.

ANSWER: Lupin's incorporation by reference of "Paragraphs 1-34" requires no response. To the extent a response is required, Elan and Fournier hereby incorporate their responses to the allegations in paragraphs 1-34 above.

36. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the invalidity of the claims of the '802 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

ANSWER: Paragraph 36 states a legal conclusion for which no response is required. To the extent that a response is required, Elan and Fournier admit that an actual controversy exists regarding the validity of the '802 patent. Elan and Fournier otherwise deny the allegations in paragraph 36.

37. The claims of the '802 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq.*

ANSWER: Denied.

38. Lupin is entitled to a declaration that the claims of the '802 patent are invalid.

ANSWER: Denied.

Elan and Fournier deny that Lupin is entitled to any of the relief requested in its prayer for relief, or to any relief whatsoever.

Any allegation of the Counterclaims not expressly admitted herein is hereby denied.

WHEREFORE, Elan and Fournier respectfully request the following relief:

A. An order dismissing each of Lupin's counterclaims, with prejudice, and denying all relief sought by Lupin;

B. A judgment that Lupin has infringed the '249 and '802 patents;

C. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 90-856 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), be a date which is not earlier than the expiration date of the '249 and '802 patents;

**D. An injunction, pursuant to 35 U.S.C. § 271(e)(4)(B),
restraining and enjoining Lupin and its officers, agents, attorneys and
employees, and those acting in privity or concert with them, from
infringement of the '249 and '802 patents for the full terms thereof;**

**E. A declaration that this is an exceptional case and an award
of attorneys' fees pursuant to 35 U.S.C. § 285;**

F. Costs and expenses in this action; and

**G. Such other and further relief as the Court may deem just
and proper.**

Respectfully submitted,

/s Gerald Krovatin
Gerald Krovatin, Esq.
KROVATIN KLINGEMAN LLC
744 Broad Street, Suite 1903
Newark, NJ 07102
(973) 424-9777

Glenn J. Pfadenhauer
Kevin Hardy
Anne M. Rucker
Scott K. Dasovich
Kendra P. Robins
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, D.C. 20005
(202) 434-5000

Timothy C. Bickham
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, NW
Washington, DC 20036-1795
(202) 429-5517

*Attorneys for Plaintiff
Fournier Laboratories Ireland Ltd.*

/s William J. Heller
William J. Heller
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 622-4444

Jack B. Blumenfeld
Maryellen Noreika
MORRIS, NICHOLS, ARSHT &
TUNNELL LLP
1201 North Market Street, 18th Floor
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200

*Attorneys for Plaintiff
Elan Pharma International Ltd.*

Dated: April 14, 2010

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I have this 14th day of April, 2010, caused a true and correct copy of the foregoing to be served upon all counsel of record via CM/ECF.

/s Gerald Krovatin

Gerald Krovatin